

### **REMARKS**

The Final Office Action mailed November 25, 2008, has been received and reviewed. Claims 1, 4, 6, 7, 9-12, 15-23 and 26-38 are pending in the subject application. All pending claims stand rejected under 35 U.S.C. § 102(e). In response, it is proposed that each of claims 1, 4, 6, 7, 9, 12, 15, 17-20, 23, 26, 28-31, and 34-38 be amended as set forth herein. As such, upon entry of the proposed amendments, claims 1, 4, 6, 7, 9-12, 15-23 and 26-38 will remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the proposed amendments and the following remarks.

#### **Support for Claim Amendments**

Each of independent claims 1, 12, and 23 has been amended as set forth herein. In particular, the independent claims are amended herein to recite a clarification of the process of verifying a preliminary billing item against a compliance template, and in particular, clarifies the configuration of the compliance template itself. Support for these claim amendments may be found in the Specification, for example, at pages 5 and 6, paragraphs [0026] – [0028].

Further, claims 7, 9, 12, 30, 31, and 34 are amended to recite a form of supporting documentation, which is absent from the preliminary billing item, that is used to satisfy the criteria of the compliance template that is unsatisfied by the preliminary billing item. Support for these claim amendments may be found in the Specification, for example, at pages 6-9, paragraphs [0028] – [0032].

In general, amendments to the claimed subject matter is not "new matter" within meaning of 35 U.S.C. § 132 or Rule 118 of Patent Office Rules of Practice, unless it discloses an invention, process, or apparatus not theretofore described. Further, if later-submitted material

simply clarifies or completes prior disclosure it cannot be treated as "new matter."<sup>1</sup> Accordingly, because these amendments are either implicit or clearly expressed in the procedure of determining compliance of the preliminary billing item, as disclosed in the Detailed Description, the newly recited subject matter does not constitute new matter.

### **Rejections based on 35 U.S.C. § 102**

#### **A.) Applicable Authority**

Anticipation “requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee.”<sup>2</sup> “[P]rior knowledge by others requires that all of the elements and limitations of the claimed subject matter must be expressly or inherently described in a single prior art reference.”<sup>3</sup> “The single reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention.”<sup>4</sup>

#### **B.) Anticipation Rejection Based on U.S. Publication No. 2003/0191667 to Fitzgerald**

Claims 1, 4, 6, 7, 9-12, 15-23 and 26-38 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Publication No. 2003/0191667 to Fitzgerald (hereinafter the “Fitzgerald reference”). As the Fitzgerald reference does not describe, either expressly or

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<sup>1</sup> *Triax Co. v Hartman Metal Fabricators, Inc.*, 479 F.2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).

<sup>2</sup> MPEP § 2131, *passim*; *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995).

<sup>3</sup> *Elan Pharms., Inc. v. Mayo Foundation for Medical Educ. & Research*, 304 F.2d 1221, 1227 (Fed. Cir. 2002) (citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)).

<sup>4</sup> *Id.* (emphasis added)(citing *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)). See also, *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

inherently, each and every element the rejected claims 1, 4, 6-7, 9-12, 15-23 and 26-38, the Applicant respectfully traverses the rejection of these claims, as hereinafter set forth.

Independent claim 1, as amended hereinabove, recites a computer system for conditioning clinically related billing items, where the computer system comprises a conditioning engine that performs a variety of operations. In one instance, the conditioning engine is configured for analyzing (as a condition precedent to transmitting the billing item to a paying party) a preliminary billing item by comparison against a compliance template to determine compliance therewith.

As recommended by the Examiner on page 4, lines 11 and 12, of the Office Action, the compliance template is positively recited as part of the claimed computer system. Pursuant to this recommendation, the amended claim 1 recites a computer system comprising “the compliance template that includes *criteria configured based on the preliminary billing item and at least one regulatory guideline and comprises data fields*, which correspond to each of the criteria, respectively, *that record information that satisfies the criteria*, wherein the criteria, when satisfied, qualify the preliminary billing item under the at least one regulatory guideline” (emphasis added). In this way, the compliance template is claimed as a structural element, where the compliance template is required to have criteria and corresponding data fields that are based on (a) the preliminary billing item, and (b) at least one regulatory guideline. Further, as claimed, the compliance template must include criteria (e.g., criteria of compliance template 122 of FIG. 2 that includes physician referral, physician orders, etc.) that is dynamically selected based on, in part, attributes of the preliminary billing item.

In a substantially similar manner, independent claims 12 and 23, as amended herein, positively recite the compliance template as a structural element. Specifically, amended claims 12 and 23 recite, in part, “a compliance template,” where “the compliance template

includes criteria configured based on the preliminary billing item and at least one regulatory guideline and includes data fields, which correspond to each of the criteria, respectively, that record information that satisfies the criteria, wherein the criteria, when satisfied, qualify the preliminary billing item under the at least one regulatory guideline.”

The Fitzgerald reference does not disclose a process for determining compliance of a preliminary billing item that includes comparing the preliminary billing item against a compliance template that has the features of (a) criteria configured based on the preliminary billing item and at least one regulatory guideline, and (b) data fields, which correspond to each of the criteria, respectively, that record information that satisfies the criteria. Instead, Fitzgerald evaluates claim data—related to provision of healthcare—for accuracy by using rules to validate the claim data for processing payment.<sup>5</sup> These rules are derived from a repository and may be continuously updated and maintained.<sup>6</sup> Further, these rules may contain one or more tests to identify a true condition and initiate a first set of actions or a false condition and initiate a second set of actions.<sup>7</sup> However, these rules are not comparable to the positively claimed structure of the compliance template. Moreover, the rules are not selected based on both (a) the preliminary billing item and (b) at least one regulatory guideline, but generally derived from a repository, as discussed above. As such, for at least this reason, the Fitzgerald reference does not teach each and every element of the independent claims 1, 12, and 23.

Accordingly, the Applicant contends that claims 1, 12, and 23 are not anticipated by Fitzgerald and are in condition for allowance. Each of claims 4, 6, 7, 9-11, 15-22 and 26-38

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<sup>5</sup> See *Fitzgerald reference* at pg. 3, ¶ [0025].

<sup>6</sup> *Id.* at pg. 3, ¶ [0026].

<sup>7</sup> *Id.* at pg. 4, ¶ [0033].

is believed to be in condition for allowance based, in part, upon their dependency from claims 1, 12, and 23, respectively, and such favorable action is respectfully requested.<sup>8</sup>

Further, independent claim 12, as amended herein, recites a procedure for “determining that the preliminary billing item complies with the at least one regulatory guideline upon performing a compliance process.” In particular, the compliance process includes, *inter alia*, “(a) interrogating a compliance template,” “(c) determining that some of the criteria remains unsatisfied upon comparison of the compliance template to the preliminary billing item,” and “(c) *satisfying the unsatisfied criteria by verifying the existence of affirming data elements that support the preliminary billing item*, wherein the affirming data elements provide a record of services delivered with respect to the clinical event in the form of supporting documentation, *which is absent from the preliminary billing item*, wherein verifying comprises automatically scanning ancillary clinical data stores for the supporting documentation and utilizing the supporting documentation to satisfy the criteria of the compliance template that is unsatisfied by the preliminary billing item” (emphasis added).

In this way, if the records included in the preliminary billing item do not satisfy each and every criteria of the compliance template, then affirming data elements are searched for within the ancillary clinical data stores. Moreover, the affirming data elements, as defined by the claims, are (a) “absent from the preliminary billing item,” and (b) utilized to “satisfy the criteria of the compliance template that is unsatisfied by the preliminary billing item.”

The Examiner states in the Office Action at page 12, lines 18-21, that no specific definition for the affirming data elements has been previously claimed and that “any data capable of being used to verify [a] claim may be reasonably interpreted to be ‘evidentiary support’ and ‘affirming data elements’.” As amended, claim 12 defines the “affirming data elements” such

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<sup>8</sup>See 37 C.F.R. § 1.75(c) (2006).

that they cannot be taught by the “collated claim data” of Fitzgerald.<sup>9</sup> In other words, the collated claim data is cited by the Examiner as comparable to the preliminary billing item, but the affirming data elements are absent from the preliminary billing item and, thus, are a separate item. Accordingly, proper interpretation of amended claim 12 requires that the affirming data elements are considered additional data other than the preliminary billing item and may not be anticipated by only the received claim data of Fitzgerald.

Further, the affirming data elements are used to “satisfy the criteria of the compliance template that is unsatisfied by the preliminary billing item.” In contrast, the Fitzgerald simply applies rules that administer a test on a billing item, where the outcome of the test is either a “true” or “false” result.<sup>10</sup> As such, for at least these reasons, claim 12 is not taught by Fitzgerald and is in condition for allowance.

In a substantial similar manner, dependent claim 34 recites the affirming data elements as being absent from the preliminary billing item, while dependent claim 4 recites the affirming data elements as being utilized for satisfying the unsatisfied criteria of the compliance template. As such, for at least these reasons, claims 4 and 34 are not taught by Fitzgerald and are in condition for allowance.

Moreover, independent claim 12, as amended herein, recites that upon determining that the preliminary billing item complies with the at least one regulatory guideline, the method includes “generating a verified billing item from the compliant preliminary billing item,” where “the verified billing item includes *annotations to the supporting documentation utilized to satisfy the unsatisfied criteria of the compliance template*” (emphasis added). In this way, the documentation (a) used to support the affirming data elements, which are distinct from the preliminary billing item, and (b) used to satisfy the unsatisfied criteria of the compliance

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<sup>9</sup> See Fitzgerald reference at pg. 6, ¶ [0062].

template are referenced by the verified billing item. Subsequently, the method includes the step of “transmitting the verified billing item to the paying party.”

The Examiner states that the documentation previous recited in the claims was considered to be “already attached as part of the collated claim data.”<sup>11</sup> As amended, claim 12 defines the documentation as supporting the affirming data elements, which are not part of the preliminary billing item. Accordingly, the collated claim data does not encompass both the preliminary billing item, the supporting documents, and the annotation within the verified billing item to the supporting documents. As such, for at least these reasons, claim 12 is not taught by Fitzgerald and is in condition for allowance.

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<sup>10</sup> *Id.* at pg. 3, ¶ [0025].

<sup>11</sup> *See* Office Action at page 13, lines 8-11.

### **CONCLUSION**

For at least the reasons stated above, upon entry of the amendments, it is believed that claims 1, 4, 6, 7, 9-12, 15-23 and 26-38 will be in condition for allowance. As such, Applicants respectfully request entry of the amendments, withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or btabor@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNL110509.

Respectfully submitted,

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